IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA	)	
	)	
v.	)	CRIMINAL No. 14-158
	)	
ZUNED SUNESRA	)	

DEFENDANT ZUNED SUNESRA'S
SUPPLEMENTAL MEMORANDUM OF LAW IN OPPOSITION
TO GOVERNMENT'S MOTION FOR PRELIMINARY RULING

Defendant, Zuned Sunesra, by and through his undersigned counsel, submits this Supplemental Memorandum of Law in opposition to the Motion:

1. The government filed a Motion for Preliminary Ruling (see Doc. # 64, the "Motion") on November 3, 2014.

2. Defendant filed an Opposition on November 17, 2014 (see Doc. # 72).

3. The government prematurely seeks by its Motion to obtain a jury instruction on "misbranding" under the Federal Food, Drug and Cosmetic Act ("FDCA").

4. Defendant files this supplemental memorandum to make an admittedly fine but nonetheless important point: "misbranding" is not an offense under the FDCA. A "misbranded" drug is merely a characteristic of a prescription drug which may not be introduced into interstate commerce. 21 U.S.C. §331(a).

5. The government seeks by its proposed jury instruction to stretch the FDCA beyond its reach. The FDCA does not regulate drugs in international commerce. Pharmacies operating in foreign countries may dispense drugs deemed misbranded by the FDCA without violating the FDCA.

6. The cases cited by the government in its Motion do not address this issue in the context of a criminal prosecution. The government cites United States v. Caronia, 703 F.3d 149, 172 (2d Cir. 2012) for the proposition that the FDCA prohibits conduct by pharmacies in India if they introduce or "cause" the introduction of misbranded drugs into U.S. interstate commerce. (Motion, at ¶5, n.1). First, Caronia does not address the question of whether a foreign pharmacy violates §331(a) if it dispenses a drug to an individual who imports the drug into the United States. Caronia was a consultant hired by a U.S.-based pharmaceutical company to promote a drug in the Queens, Nassau, and Suffolk counties of New York. In any event, the government cites to the dissent in Caronia for approval of the trial court's jury instruction on conspiracy to violate §331(a). This is indeed shaky ground. The Second Circuit overturned Caronia's conviction because the trial court had incorrectly instructed the jury that off-label promotion was a basis for conviction. Id. at 160. The Second Circuit accords no precedential weight to dissents, and this Court should not either.

7. The government also cites In re Canadian Import Antitrust Litigation, 385 F. Supp. 2d 930 (D. Minn. 2005) as support for an instruction that the absence of an "Rx Only" symbol constitutes "misbranding." In re Canadian was a civil antitrust action brought by U.S. consumers against drug companies. The plaintiffs alleged the pharmaceutical companies had colluded in violation of the Sherman Act to prevent the importation of lower-cost prescription drugs. The court dismissed the consumers' federal antitrust claims on the ground that their activity—the importation of prescription drugs from Canada for personal use in the United States—introduced into interstate commerce drugs which failed to meet the FDCA's labeling requirements. But the court firmly grounded its ruling on the act of importation and introduction into interstate commerce: "the Court agrees . . . that prescription drugs imported from Canada for

personal use in the United States are misbranded. The Court also agrees . . . that the transport of drugs for personal use into the United States constitutes an "introduction into interstate commerce" under the FFDCA . . . ." Id. at 934. The prohibited act was the importation, not misbranding in a foreign country. A jury instruction on §331(a) must, to be fair, note that a misbranded drug in a foreign country by itself is not a crime. It is the act of importation or the introduction into the United States which violates the law.

8. The remaining cases cited by the government do not inform the discussion because they concern the introduction into interstate commerce of drugs by individuals and entities operating in the United States:

a. United States v. Williams, 549 Fed. App'x 813 (10th Cir. 2013) (*cited in ¶ 5 of the government's Motion*) – fulfillment pharmacy operated in Oklahoma, which shipped within the United States;

b. United States v. Patwardhan, 422 Fed. App'x 614 (9th Cir. 2011) (*cited in ¶ 5 of the government's Motion*) – doctor in the United States provided non-FDA approved drugs to patients;

c. United States v. Regenerative Sciences, LLC, 741 F.3d 1314 (D.C. Cir. 2014) (*cited in ¶ 5 of the government's Motion*) – Colorado medical clinic that serviced United States patients;

d. United States v. Goldberg, 538 F.3d 280 (3d Cir. 2008) (*cited in ¶ 7 of the government's Motion*) – domestic sale of veterinary grade prescription drugs to horse owners; and

e. United States v. Arlen, 947 F.2d 139 (5th Cir. 1991) (*cited in ¶ 7 of the government's Motion*) – Texas-based bodybuilder who supplied steroids to customers through the mail.

9. Defendant urges the Court not to rule on jury instructions at this time. Courts typically rule on jury instructions at the close of the evidence. This time-honored practice gives Courts the benefit of understanding how the evidence informs the issues.

10. Finally, Defendant notes the Court has not yet set a trial date. Defendant seeks leave of the Court to raise additional objections to any proposed jury instructions in the normal course.

WHEREFORE, Defendant, Zuned Sunesra, submits this Supplemental Memorandum of Law in Opposition to the Government's Motion for Preliminary Ruling.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of this Supplemental Memorandum of Law in Opposition to the Government's Motion for Preliminary Ruling has been served on this 19th day of February, 2014, upon the following parties via the Court's CM/ECF System, and is otherwise available for viewing and downloading on the CM/ECF System:

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